

Remarks

Claims 1, 4-7, 11, 14-17 and 42-46 are pending in the instant application. Claims 11, 14-17 and 42-46 are withdrawn from further consideration pursuant to the provisions of 37 CFR §1.142(b), as being drawn to nonelected inventions. Applicants have hereinabove cancelled claim 7 without prejudice or disclaimer to their right to pursue the subject matter of these claims in a future application. In addition, applicants have hereinabove amended claims 1 and 5. Support for the amendments to claim 1 may be found, *inter alia*, in the subject specification as follows: claim 1: page 6, line 27 – page 7, line 4. The remaining changes to the claims merely introduce minor grammatical and format changes. This Amendment does not involve any issue of new matter. Therefore, entry of this Amendment is respectfully requested such that claims 1 and 4-6 will be pending and under examination.

Rejection Under 35 U.S.C. §112, first paragraph

Enablement

The Examiner rejected claims 1 and 4-7 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner alleged that the claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner alleged that the present specification lacks guidance and/or working examples of the utilization of all CCR5 antagonist compounds in the prevention of all maladies involving a stress response and, thus, does not enable those skilled in the art to which it pertains to use the invention commensurate in scope with these claims.

In response, applicants have hereinabove cancelled claim 7 without prejudice or disclaimer. Therefore, the rejection thereof is now moot.

With respect to the rejection of the remaining claims, applicants respectfully traverse. Nevertheless, applicants without conceding the correctness of the Examiner's rejection and to expedite prosecution of the subject application, have hereinabove amended claim 1. Claim 1, as amended, no longer recites "stress response" but instead now recites specific disorders to be treated which are described in the instant specification. In addition, claim 1, as amended no longer recites prevention of

stress responses. Finally, claim 1 has been amended such that it now recites the specific CCR5 antagonist compounds described in the instant specification. In light of these amendments to claim 1, applicants maintain that one of skill in the art could make and use the claimed invention based on the teachings of the subject specification.

In view of the above remarks, applicants maintain that claim 1, and the claims which depend therefrom, satisfy the Examiner's rejection. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Written Description

The Examiner rejected claims 1 and 4-7 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. The Examiner alleged that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner stated that no specific CCR5 antagonist is claimed.

In response, applicants have hereinabove cancelled claim 7 without prejudice or disclaimer. Therefore, the rejection thereof is now moot.

With respect to the rejection of the remaining claims, applicants respectfully traverse. Applicants contend that the Examiner has failed to make out a *prima facie* case to support his allegation that applicants have failed to comply with the written description requirement. Rather, the Examiner has only provided summary allegations that no specific CCR5 antagonist is claimed and that the disclosed Formula I could encompass a multitude of possible chemical structures. Applicants contend that the Examiner's position is unsupported. Indeed, the points made by the Examiner support that the claims and specification do comply with the written description requirement.

Particularly, the subject application discloses a specific compound in the Examples, i.e. Compound A. Further the compounds of the disclosed Formulas, i.e. Formula I and Formula II, provide a range of representative compounds that can support that applicants are in possession of the full scope of the term "CCR5 antagonist". Furthermore, the Examiner acknowledges that there are

known CCR5 antagonists at page 17 of the June 12, 2008 Office Action. Thus, upon review of the present specification as a whole, applicants contend that one of ordinary skill in the art would clearly recognize that applicants were in possession of the full scope of the term "CCR5 antagonist".

Applicants also note that on page 30, lines 1-6, of the subject specification there are several examples of issued patents and published patent applications in which the compounds that are disclosed therein are indicated as CCR5 antagonists. These patents include U.S. Patent Nos. 6,013,644; 5,962,462; 5,919,766; 6,124,319; 6,136,827; 6,166,037; 6,140,349; 6,265,434; 6,248,775; and PCT Publication Nos. WO00/59497; WO99/76512; WO00/76511; WO00/76973; WO00/76513; and WO00/76514.

Other CCR5 antagonists include: MARAVIROC (from Pfizer), TAK-779 (from Takeda), INCB9471 (from Incyte Corp.), and VICRIVIROC (from Schering Plough). Further at page 30, lines 7-18, *inter alia*, peptide antagonists of CCR5 are disclosed. Also, disclosed at page 34, lines 6-14, are antibody CCR5 antagonists. Accordingly, in view of the multitude of examples of CCR5 antagonists provided in the instant disclosure and known in the art, it is believed that one of ordinary skill in the art would clearly appreciate that applicants were in possession of the full scope of the term "CCR5 antagonist" as of the priority date of the instant application.

In view of the above remarks, applicants maintain that claim 1, and the claims which depend therefrom, satisfy the Examiner's rejection. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejection Under 35 U.S.C. §102(b)

The Examiner rejected claims 1, 4 and 7 under 35 U.S.C. §102(b) as allegedly being anticipated by Finke et al. (WO 00/76972). Specifically, the Examiner stated that Finke et al. teaches compounds which include the instantly elected CCR5 antagonist, compound A, for treatment of diseases and conditions associated with inflammation and infection. The Examiner alleged that treatment of these diseases and conditions all read on the instant claim of treating "stress response."

In response, applicants have hereinabove cancelled claim 7 without prejudice or disclaimer. Therefore, the rejection thereof is now moot.

With respect to the remaining claims, applicants respectfully traverse. Nevertheless, applicants without conceding the correctness of the Examiner's rejection and to expedite prosecution of the subject application, have hereinabove amended claim 1. Claim 1, as amended, recites the use of a CCR5 antagonist to treat "a response selected from trauma, a physiopathological state, hyperthermia, hypothermia, hypertension, hypotension, malaise, tissue damage, organ damage, organ failure and fever". Finke et al. does not describe the use of a CCR5 antagonist to treat the disorders/conditions set forth in amended claim 1. Therefore, Finke et al. does not teach each and every element of claim 1. Accordingly, applicants maintain that claim 1, as amended, and claim 4 which depends therefrom, are novel over Finke et al. and satisfy the requirements of 35 U.S.C. §102(b).

In view of the above remarks, applicants maintain that claim 1, and the claims which depend therefrom, satisfy the Examiner's rejection. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 1 and 4-7 under 35 U.S.C. §103(a) as allegedly being unpatentable over Finke et al.

In response, applicants have hereinabove cancelled claim 7 without prejudice or disclaimer. Therefore, the rejection thereof is now moot.

With respect to the remaining claims, applicants respectfully traverse. Nevertheless, applicants without conceding the correctness of the Examiner's rejection and to expedite prosecution of the subject application, have hereinabove amended claim 1. Claim 1, as amended, recites the use of a CCR5 antagonist to treat "a response selected from trauma, a physiopathological state, hyperthermia, hypothermia, hypertension, hypotension, malaise, tissue damage, organ damage, organ failure and fever". Finke et al. does not describe the use of a CCR5 antagonist to treat the disorders/conditions set forth in amended claim 1. Therefore, Finke et al. does not teach each and every element of claim 1 and consequently is not prior art against claims 1 and 4-6. Since Finke et al. is not prior art against claims 1 and 4-6, applicants' claimed invention cannot be obvious in light of its teachings.

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In light of the above remarks, applicants maintain that claim 1, and the claims which depend therefrom, satisfy the requirements of 35 U.S.C. §103(a). Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Summary

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the various grounds of rejection and earnestly solicit allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone her at the number provided below.

No fee, other than the \$130.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the large entity amount of such fee to Deposit Account No. 13-2755 referencing attorney docket number 21067YP.

Respectfully submitted,

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